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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed November 16, 2006. Applicant's Exhibits 1-3, (Lew, 2002, Brutto, 2002 and Flalkner vs. Inglis) filed November 16, 2006 are also are acknowledged. Claims 1, 9 and 16 have been amended. Claim 29 has been added. Claims 21-28 have been cancelled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendments and response the following rejections are withdrawn:

(a) rejection of claims 1-20 under 35 U.S.C. 112 first paragraph, paragraph 6, pages 4-6 is withdrawn.

(b) rejection of claims 1-20 under 35 U.S.C. 102(b), paragraph 10, pages 9-10 is withdrawn.

Rejections Maintained

4. The rejection double patenting rejection is maintained for claims 1-20 for the reasons set forth on pages 3-4, paragraph 5 of the previous Office action.

The rejection was on the grounds that the claims are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/039, 506 filed January 18, 2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets claims (claims 1-20 of this application and claims 1-17 of copending Application No. 11/039, 506) are drawn to a method of treating medication overuse patients by administering botulinum toxin to the patients. It should be noted that "triptan medication overuse patients" would be a species of the genus "medication overuse patients". Therefore, the scope of the claims 1-20 of this application would encompass the scope of claims 1-17 of copending Application No. 11/039, 506.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant Arguments

Applicant urges that the two inventions differ because the current invention (application 10/789, 180) is directed to a method of treating pain medication overuse disorder caused by overuse of acute pain medication and co-pending application 11, 039,506 is directed to treating headaches in triptan medication overusers. Applicant urges that the current invention is directed to treating a disorder and the invention of application 11, 039,506 is directed to headaches.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed November 16, 2006 have been fully considered but they are not persuasive.

It is the Examiner's position that the double patenting rejection is proper. The current invention is direct to treating an acute pain medication disorder. However, the invention of application 11, 039,506 is directed to treating a headache in triptan medication overuse patients as well as reducing (treating) the use of triptan medication to treat a headache. Thus, both methods are directed to treating or reducing the use of acute overuse medication in patients. It is noteworthy, to remember that triptan medications are a species of the acute medication genus.

5. The rejection under 35 U.S.C. 102(a) is maintained for claims 1-3, 10-17, 19-20 and newly submitted 29 for the reasons set forth on page 7, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Schim teaches a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 51). Schim teaches this method because Schim teaches that botulinum toxin was administered to patients with and without analgesic overuse (Study 3, page 51). Schim teaches that botulinum toxin was effective in treating patients with medication overuse disorder (page 51).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Schim does not teach or suggest treatment of an acute pain medication overuse disorder wherein the pain experienced by the patient is caused by overuse of acute pain medication. Applicant urges that there is no teaching or suggestion in Schim that the headaches suffered by the patients were caused by the intake of medication but rather that some patients had analgesic overuse. Applicant urges that the claims have been amended to include the limitation wherein the patient experiences pain after intake of acute pain medication.

Applicant urges that Schim does not meet the limitation of claim 29 which is the method of claim 16, wherein the patient experiences a headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed November 16, 2006 have been fully considered but they are not persuasive.

Schim teaches administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication such as triptans) (see case study 3, page 51). It should be noted that Schim teaches that botulinum toxin therapy reduces the use of pain medication as well as reduces the frequency of headaches (page 52). Thus, Schim teaches that acute medication overuse patients that have been given botulinum therapy experience

headaches (pain) after the intake of acute pain medication. Schim teaches that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Schim teaches all limitations of claim 29 because the patients used in the studies of Schim are analgesic medication overusers and as set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that experiences a chronic headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-20 and newly submitted claim 29 for the reasons set forth on page 7, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Tepper et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 715). Tepper et al teach that the patients were administered 100 units of botulinum toxin A (page 715). Tepper et al teach that botulinum toxin was effective in treating patients with medication overuse disorder (page 715).

Applicant's Arguments

Applicant urges that Tepper et al do not teach or suggest treatment of an acute pain medication overuse disorder wherein the pain experienced by the patient is caused by overuse of acute pain medication. Applicant urges that there is no teaching or suggestion in Tepper et al that the headaches suffered by

the patients were caused by the intake of medication but rather that some patients had analgesic overuse. Applicant urges that the claims have been amended to include the limitation wherein the patient experiences pain after intake of acute pain medication.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed November 16, 2006 have been fully considered but they are not persuasive. Tepper et al teach administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication) (see Abstract). It should be noted that Tepper et al teach that botulinum toxin therapy reduces the use of pain medication as well as reduces the frequency of pain, intensity of pain, days with severe headache and headache intensity (Abstract). Tepper et al teach that acute medication overuse patients that have been given botulinum therapy experience headaches (pain) after the intake of acute pain medication. Therefore, Tepper et al teach that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Tepper et al teach all limitations of claim 29 because the patients used in the studies of Tepper et al are analgesic medication overusers and as set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that

experiences a chronic headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months.

7. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-20 and newly submitted claimed 29 for the reasons set forth on pages 7-8, paragraph 8 of the previous Office Action.

Matthew et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (see the Abstract). Mathew et al teach that the patients with and without analgesic overuse were administered 50 to 100 units of botulinum toxin A to multiple scalp and neck sites (see the Abstract). Matthew et al teach that botulinum toxin was effective in treating patients with medication overuse by reducing the number of chronic migraine and thereby reducing the acute medication use (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Matthew et al do not teach or suggest treatment of an acute pain medication overuse disorder wherein the pain experienced by the patient is caused by overuse of acute pain medication. Applicant urges that there is no teaching or suggestion in Matthew et al that the headaches suffered by the patients were caused by the intake of medication but rather that some patients had analgesic overuse. Applicant urges that Matthew et al is direct at treating chronic migraine and not overuse medication overuse. Applicant urges

that the claims have been amended to include the limitation wherein the patient experiences pain after intake of acute pain medication.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed November 16, 2006 have been fully considered but they are not persuasive. Matthew et al teach administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication) (see Abstract). It should be noted that Tepper et al teach that botulinum toxin therapy reduces the use of pain medication as well as reduces the headache disability (Abstract). Thus, Matthew et al teach that acute medication overuse patients that have been given botulinum therapy experience headaches (pain) after the intake of acute pain medication. Matthew et al teach that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Tepper et al teach all limitations of claim 29 because the patients used in the studies of Tepper et al are analgesic medication overusers and as set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that experiences a chronic headache frequency greater than 15 days per month after

the intake of analgesics or ergots more than 15 times per month for at least 3 months.

Status of Claims

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 272–8200.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Thursday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
February 1, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER